REMARKS

Claims 1-6, 8, 11, 12 and 19-24 currently appear in this application. The Office Action of December 26, 2006 been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicant respectfully requests favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Response to Election/Restriction

It is noted that the restriction/election requirement has been made final. Accordingly, nonelected claims 9, 10 and 13-18 have been cancelled.

It is not understood why claims 6 and 7 are considered to be withdrawn, as the restriction requirement stated that claims 1-8, 11 and 12 were the claims comprising Group I, the elected group. Accordingly, it is respectfully requested that claim 6 be examined on the merits, as claim 6 was part of the elected group of claims.

Amendments to the Claims

Claims 1, 11 and claims dependent thereon have been amended to recite that the protein is a recombinant protein. Support for this amendment can be found in the specification as filed at page 6, lines 10-12. New claim 19 has been added,

support for which can be found in the specification as field at page 6, line 19. Claim 18 has been cancelled since it is of the same scope as claim 5.

New claims 20-24 have been added to recite a solution consisting essentially of a protein and a pharmaceutically acceptable carrier. Support for this can be found in the specification as filed at page 12, lines 17-24 and page 15, lines 15-19 describing an injectable EPO solution, which, of course, must be pharmaceutically acceptable. Support for "aqueous solution" can be found in the specification as filed at page 16, lines 16-21.

The Claimed Invention

What is claimed herein relates to a method for stabilizing a solution containing a recombinant protein. The characteristic feature of the method is to store the solution under magnetic field lines, whereby the solution remains stable during storage and the protein concentration of the solution is stable during storage. Storing the solution under the influence of a magnetic field suppresses association of the proteins, such as dimerization (refer to page 15, lines 12-15 and page 22, lines 14-19).

As explained in the background art section of the specification, association of proteins in a solution has an adverse effect on the stability of the solution formulation. Therefore, the present inventors have suppressed such association, particularly for pharmaceuticals, by storing the protein solution formulations under the influence of magnetic fields.

Art Rejections

Claims 1, 3-5 11 and 18 are rejecter under 35 U.S.C. 102(b) as being anticipated by Castle, U.S. 5,261,874.

This rejection is respectfully traversed. The Examiner asserts that Castle discloses that blood is subjected to electromagnetic fields to radiate foreign organisms in the blood, whereby the longevity of the blood would be increased.

Actually, Castle teaches that blood can be subjected to a magnetic field. However, there is nothing in Castle that teaches or suggests that a solution formulation containing a protein can be stabilized by subjecting the solution to an electromagnetic field, as Castle merely teaches that blood is irradiated for killing viruses in blood, killing bacteria in blood, monitoring blood for medical purposes, genetic modification of blood, and analyzing and/or treating blood components (column 4, lines 31-35). While this may render the blood sterile, Castle is completely silent about

increasing the longevity of the blood by suppressing protein association. There is nothing in Castle relating to preventing protein association, only to killing viruses or bacteria or for monitoring blood.

As mentioned above, the claims are limited to stabilizing recombinant proteins, which are clearly different from the proteins in blood in Castle. In general, a recombinant protein is more unstable that are naturally occurring proteins such as blood proteins, partly because of the environment in which each protein exists.

Further, in the case of a solution formulation of a recombinant protein, generally, the formulation substantially contains only the recombinant protein as the protein material in the solution (such as, for example, claim 18). The recombinant protein is selected based upon the purpose for which the recombinant protein is used, such as for pharmaceuticals. Comparing the environment of the recombinant protein in such a solution and the types of proteins and other components found in blood, it is clear that the recombination protein formulation is not at all the same as blood. The recombination protein is almost always the sole component in a formulation, and because of such an environment, a recombinant protein in a formulation solution is relatively unstable, particularly since it is subject to association. Taking this

property of a recombinant protein solution into consideration, it is respectfully submitted that it is almost impossible for one skilled in the art to expect that stabilizing a recombinant protein solution formulation can be accomplished by storing the solution under magnetic field conditions.

It should also be appreciated that the presently claimed method relates to **storing** the protein solution under the influence of a magnetic field. Castle, on the other hand, discloses **treating** blood extracorporeally with energy. This treatment is not ongoing as would be in the case of stored liquids, but is directed to treating blood in a patient that has been temporarily diverted from the patient's circulatory system, after which treatment it is returned to the patient. This is not at all the same as storing the blood under a magnetic field. As it has been demonstrated that protein solution formulations can be stored for weeks or months, it is clear that this is not the same method as Castle's merely treating the blood with radiation.

Claims 2 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castle et al. The Examiner's position is that the strength of the magnetic field is not critical. With regard to claim 12, the Examiner states that Castle teaches that the blood not be recirculated to the animal.

This rejection is respectfully traversed. Whether or not the blood is returned to the animal, there is nothing in Castle that suggests **storing** protein solutions under the influence of a magnetic field. Castle is merely concerned with destroying bacteria or viruses, or in analyzing blood. There is no teaching or suggestion in Castle of storing blood.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Castle in view of Cohen, U.S. 3,308,809.

This rejection is respectfully traversed. As noted above, Castle has nothing at all to do with storing recombinant proteins. Cohen merely discloses that blood can be stored in a syringe. However, there is nothing in Castle about storing blood under the influence of a magnetic field, such storage being over period of weeks or months. Therefore, the fact that blood can be stored in a syringe as taught by Cohen is irrelevant.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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